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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,596	10/18/2005	Rena Nishizawa	Q90950	4644

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
MURRAY, JEEFREY H	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,596	NISHIZAWA, RENA	
	Examiner	Art Unit	
	Jeffrey H. Murray	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is an imidazolidine-2,4-dione derivative.

II. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a pyrazolidin-3-one derivative.

III. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a piperazine-2,6-dione derivative.

IV. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a piperazine derivative.

V. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a piperazin-2-one derivative.

VI. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a tetrahydropyrimidin-4(1H)-one derivative.

VII. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a 1,5-diazepane-2,6-dione derivative.

VIII. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a tetrahydropyrimidin-2(1H)-one derivative.

IX. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a 1,4-oxazepan-5-one derivative.

X. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a 1,4-diazepane-2,5-dione derivative.

XI. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is a 1,3-diazepan-2-one derivative.

XII. A compound drawn to formula (I), according to Claims 1-9, wherein Ring A is an imidazolidin-2-one derivative.

XIII. A composition drawn to the spiro-piperidine compound of the formula (I), according to Claims 1, 10-18.

XIV. A method drawn to preventing and/or treating diseases caused by CCR5 or CCR2, according to Claim 19.

2. The inventions listed as Groups I - XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

WO 03/020721 A1 and EP 1423391 A1 can be cited as prior art against Claims 1-7 and 9 of this application. WO 02/06234 A1 and EP 1302462 A1 can be cited as prior art against Claims 1-6 of this application. JP 11-512723 A and US 6291469 B1 can be cited as prior art against Claims 1-7, 10, and 17 of this application. JP 49-72332 A can be cited as prior art against Claims 1-6 of this application. JP 49-13184 A can also be

cited as prior art against Claims 1-6 of this application. JP 04-18092 can be cited as prior art against Claims 1-6 and 10 of this application. JP 2003-104884 A and US 2002189124 A1 can be cited as prior art against Claims 1-6, 10 and 17 of this application. JP 08-512034 and WO 95/01358 A1 can be cited as prior art against Claims 1-6 of this application. JP 2002-348288 A can be cited as prior art against Claims 1-16 18 and 20 of this application.

Groups I – XII lack unity with Group XIII because Groups I – XII are directed towards a compound, whereas Groups XIII is directed towards a composition. Groups I – XII also lack unity from Group XIV because Groups I – XII are again directed towards a compound, whereas Group XIV is directed towards a method of using the compounds.

Groups I – XII lacks unity with each other as well. Groups I – XII are all defined as a compound of general Formula (I), which comprises of a spiro-piperidine ring in which ring A may be a heterocycle. This results in various heterocyclic ring systems being attached to the piperidine ring. In the instant case, there are 5-membered nitrogen containing rings such as imidazolidines derivatives; 6-membered nitrogen containing rings such as piperazine derivatives; and, 7-membered nitrogen containing rings such as diazepanes present. In Groups I – XII, a different ring system is present in each Group. In addition, Groups VI-IX and XI contain a ring A further condensed with an additional ring B, which may or may not be heterocyclic. This also results in a lack of unity of invention within these Groups.

Because these inventions lack unity of invention for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

3. The inventions of Groups I - XIII and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different process, such as inhibiting the human melancortin-4 receptor (MC-4R).

4. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey H. Murray whose telephone number is (571) 272-9023. The examiner can normally be reached on M-F 7:30-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811 or Cecilia Tsang can be reached at 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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